

REMARKS

As required by the Examiner, the specification has been amended to note that the examples refer to the treatment of a p75 TNFR:Fc. No new matter has been added.

Claims 25 and 52 have been amended. In addition, Applicants request that the Examiner clarify that the amendments to claims 22-25 have been entered as requested in the last response.

Enclosed herewith is a Supplemental Information Disclosure Statement.

All of the claims are rejected solely under 35 U.S.C. Section 112, second paragraph, as indefinite. With respect to the independent claims 1, 27, and 54, the Examiner states that the claims do not specify what a desired or undesired conformation of a TNF receptor is, or how such could be determined. Claims 3 and 29 are also rejected as indefinite because they encompass a protein in which at least one domain has a stable conformation and at least one domain has an unstable conformation, and it is allegedly not clear what is meant by a stable or unstable conformation. Further, claims 25 and 52 are rejected as indefinite because they encompass an isomer of a TNF receptor that has a higher binding affinity for TNF, and there are two TNF ligands, TNF-alpha and TNF-beta, so it is allegedly not clear what is being claimed. The rejections are traversed in part, and rendered moot in part by amendment.

Applicants respectfully submit that the claims reasonably apprise those of ordinary skill in the art of their scope and, therefore, serve the notice function required by Section 112, second paragraph. As described in MPEP 2173.02:

Definiteness of claim language must be analyzed, not in a vacuum, but in light of:

- (A) The content of the particular application disclosure;
- (B) The teachings of the prior art; and
- (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

Here, one of ordinary skill in the art of recombinant protein production understands what is and is not a desired conformation of a recombinant protein. This is especially so in light of the guidance in the specification, which specifically defines this term at page 3, lines 13-16: “A desired conformation for a recombinant protein is the three-dimensional structure of a protein that most closely resembles, and/or duplicates the function of, the naturally occurring domain of that protein.” Indeed, it is the goal of

those of ordinary skill in the art of recombinant protein production to obtain the desired form of the recombinant protein in a form useful for its intended purpose.

With respect to the dependent claims that recite “stable” and “unstable” conformations, the specification also provides a standard for measuring the degree intended.

The fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite under 35 U.S.C. 112, second paragraph. *Seattle Box Co., v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 221 USPQ 568 (Fed. Cir. 1984). Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification. MPEP 2173.05(b)

The Examiner’s attention is directed to page 5, line 34 to page 6, line 5, where Applicants have set out how one of ordinary skill can determine meaning of the terms “stable” and “unstable” as used in the claims. Thus, one of ordinary skill could interpret the metes and bounds of the claims so as to understand how to avoid infringement.

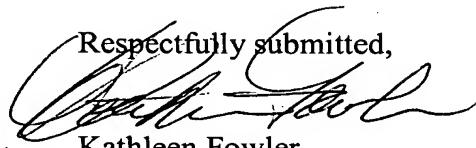
The rejection relating to claims 25 and 52 is believed rendered moot by the amendment submitted herewith. Applicants have amended these claims to recite “a TNF” rather than simply “TNF”. As the Examiner noted, there are two TNF ligands, TNF-alpha and TNF-beta, and the amendment makes clear this possibility. Applicants note that claims 26 and 53 (which are dependent upon claims 25 and 52, respectively), further recite TNF-alpha.

In view of the above, Applicants respectfully request that the rejections under 35 U.S.C. 112, second paragraph, be reconsidered and withdrawn.

CONCLUSION

Applicants submit that the presented claims are in condition for allowance. A favorable action is earnestly requested. Applicants' attorney invites the Examiner to call her at the number below if any issue remains outstanding.

Respectfully submitted,



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